United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7505C) | EPA-730-F-99-008 July 1999

New Pesticide Fact Sheet

N-Methylneodecanamide (MNDA)

Description of the Chemical

Generic Name: N-Methylneodecanamide (MNDA)

Common Name: MNDA

Trade Name: M-9011

EPA Shaughnessy Code (OPP Chemical Code): 079052

Chemical Abstracts Service (CAS) Number: 105726-67-8

Year of Initial Registration: July 1999

Pesticide Type: Insect Repellent

Manufacturer: Colgate-Palmolive Company
609 River Road,
Piscataway, NJ 08855-1343

Use Patterns and Formulations

Application Sites:	Indoor non-food use (residential homes)
Types of Formulation:	For Manufacturing Use in the formulation of multi-purpose cleaner/insect repellent products only.
Target Pest:	Cockroaches (unspecified) and ants (unspecified)
Use Patterns:	Household floors, walls, bathroom and other non-food contact surfaces.

Science Findings

Summary Statement:

N-Methylneodecanamide (MNDA) technical has a low acute oral (toxicity category III), dermal (toxicity category III), and inhalation toxicity (toxicity category IV). It is a slight dermal and ocular irritant (toxicity category IV). It is not a skin sensitizer.

There are no data gaps for subchronic toxicity guideline requirements. Subchronic toxicity at the LOAEL in the rat and dog are primarily limited to histologic liver changes. In the dogs, neurotoxicity occurred at doses that evidenced extreme toxicity resulting in lowering the doses. In the rat and rabbit developmental toxicity occurs only in the presence of maternal toxicity. There is no evidence of reproductive toxicity. There is no evidence of neurotoxicity in the rat subchronic neurotoxicity study and neurotoxicity only occurs at maternally toxicity levels in the combined developmental/developmental neurotoxicity study.

Chemical Characteristics

Technical Grade

Physical:	Liquid
Color:	Light grey
Odor:	Fruity
Melting Point:	N/A
pH:	7.8
Density:	7.5 lbs/gal.
Molecular Formula:	$C_9H_{19}CONHCH_3$ (mw = 185)
Vapor Pressure:	1.2 X 10^{-3} at 30°C.

Human Health Assessment

TOXICOLOGY CHARACTERISTICS

Acute Toxicity

In studies using laboratory animals, MNDA technical is of relatively low acute toxicity: Toxicity Category III for acute oral and acute dermal; and Toxicity Category IV for primary eye and skin irritation. The technical is not a dermal sensitizer.

[NOTE: For acute oral, dietary, mammalian:

Category I = very highly or highly toxic

Category II = moderately toxic

Category III = slightly toxic

Category IV = practically non-toxic]

The acute toxicity profile table below represents MNDA technical grade/MUP based on the following table of study results:

Guideline No.	Study type	Results	Tox Category
81-1	Acute Oral	450mg/kg<LD_{50}<1800 mg/kg	III
81-2	Acute Dermal	LD_{50}>1800 mg/kg	III
81-3	Acute Inhalation	LC_{50} > 2.4 mg/L	IV
81-4	Primary Eye Irritation	slight ocular irritant	IV
81-5	Primary Skin Irritation	slight dermal irritant	IV
81-6	Dermal Sensitization	not a sensitizer	
81-8	Acute Neurotoxicity	none	

Subchronic Toxicity

90-day feeding studies - Subchronic toxicity at the LOAEL in the **rat** (30 mg/kg/day) and **dog** (4.5 mg/kg/day) are primarily limited to histologic liver changes. There was no evidence of neurotoxicity in the subchronic neurotoxicity study in **rats**. In the **dog**, neurotoxicity occurred at much higher doses that also evidenced extreme toxicity.

90-day dermal toxicity study in rats - In a dermal subchronic toxicity study the results indicated for males the LOAEL for dermal toxicity is 1000 mg/kg/day and the NOAEL is 300 mg/kg/day. For females the LOAEL and NOAEL are 100 and 30 mg/kg/day. The NOAEL for systemic toxicity is 1000 mg/kg/day. The LOAEL was not determined.

Chronic Toxicity and Carcinogenicity

A determination of cancer potential was not made, since there are no chronic studies for MNDA (As far as toxicology data requirements, the Agency is treating this proposed registration as a non-food use). If the use pattern changes, additional data will be required to satisfy these guideline requirements.

Developmental Toxicity

In the rat and rabbit, there is developmental toxicity only at levels where maternal toxicity is present. There is no evidence of reproductive toxicity. There is no evidence of neurotoxicity in the rat dietary subchronic neurotoxicity study. Developmental neurotoxicity (evaluated in a combined developmental/developmental neurotoxicity study) does occur at maternally toxic levels and is limited to transient decreased pup motor activity only in males on day 18. Some signs of neurotoxicity were present in this study, but only in the presence of other maternal toxicity signs.

Mutagenicity

The mutagenic test battery demonstrated that MNDA is not mutagenic. Since the Agency is treating this proposed registration as a non-food use, metabolism data in laboratory animals are not required.

OCCUPATIONAL AND RESIDENTIAL EXPOSURE

Occupational Risk Estimates

This product is registered for residential use only. There is concern that this product may be used by professional house cleaning personnel. Therefore an intermediate-term and chronic (long-term) risk assessment was conducted for this scenario. The Margins of Exposure (MOE) for adult females employed by professional house cleaning personnel is 150. An acceptable MOE for MNDA is 100.

Residential Risk Estimates

The occupational and residential exposure database is satisfied based on the use of screening level assessments and information which consists of total deposition measurements of MNDA. These data were used with the Agency's Standard Operating Procedures for assessing Residential exposures (SOP) to estimate non-dietary, hand-to-mouth exposure of young children. Inhalation exposure was

addressed using the Screening-Level Consumer Inhalation Exposure Software (SCIES) floor mopping subset to predict post application air concentrations. Both the SOPs and SCIES are considered screening level assessments. Dermal exposure was not addressed as the available data indicate MNDA is not toxic via this route.

Aggregate Risk Estimates

The respective combined (oral, non-dietary and inhalation) screening-level MOE for children is 170. The combined application and post-application MOE for an adult female (other than professional house cleaning personnel) (body weight of 60 kg) for mopping floors with MNDA is 2900. Post-application is defined in this risk assessment as the period immediately after the floor was mopped. A MOE of 100 is considered acceptable.

Human Risk Assessment

The Agency Hazard Identification Assessment Review Committee (HIARC) evaluated the toxicology data base of MNDA, selected endpoints for occupational and residential exposure risk assessments, and established endpoints to be used for short-, intermediate- and, long-term oral exposure (hand-to-mouth for infants and children). The acute and chronic RfDs were not established since the Agency is treating this proposed registration as a non-food use. The Agency FQPA Safety Factor Committee evaluated the hazard and exposure data for MNDA and determined that the FQPA regulations do not apply to MNDA since the Agency is treating this proposed registration as a non-food use. However, the Committee considered the potential for sensitivity to infants and children due to oral hand-to-mouth exposure (under FIFRA) and determined that there was no indication of increased sensitivity.

The HIARC determined that short-, intermediate- and long-term dermal risk assessments are not required because no systemic toxicity was seen at 1000 mg/kg/day in a 90-day dermal toxicity study in rats indicating very low dermal absorption.

The HIARC established a short-term oral NOAEL (40 mg/kg/day from the developmental toxicity study in the rat, based on clinical signs and reduced food consumption at 125 mg/kg/day), and intermediate and long-term oral NOAELs (1.35 mg/kg/day from the subchronic dog study based on liver changes at 4.52 mg/kg/day) for "Hand-to-Mouth" exposure for infants and children.

The HIARC also determined that a risk assessment for inhalation exposure is required for all time periods. Although there is low acute inhalation toxicity (Toxicity Category IV; and no mortality at 2.4 mg/L), the high vapor pressure of the technical ($1.2x10^{-3}$ torr at 30°C) suggests an exposure potential via the inhalation route. Since there are no subchronic or chronic inhalation toxicity studies available, the HIARC recommended oral NOAELs for inhalation exposure risk assessments. The method for route-to-route extrapolation is

described later in this document. The NOAEL for short-term exposure is 40 mg/kg/day based on a developmental toxicity study in the rat and for intermediate- and long-term exposure the NOAEL is 1.35 mg/kg/day based on a subchronic dog study.

The HIARC also did not consider MNDA to be of specific neurologic concern since neurologic signs were either marginal, transient or occurred at otherwise toxic doses.

FQPA Considerations

The Agency FQPA Safety Factor Committee evaluated the hazard and exposure data for MNDA and determined that the FQPA regulations do not apply to MNDA since the Agency is treating this proposed registration as a non-food use. However, the Committee considered the potential for sensitivity to infants and children due to oral hand-to-mouth exposure (under FIFRA), and determined that there was no indication of increased sensitivity.

Environmental Fate and Ecological Effects Characteristics

The Agency has reviewed the proposed Section 3 registration for the indoor use of MNDA as a multi-purpose cleaner- insect repellent. Based on the ecological effects data submitted by the registrant, the Agency concluded that the product should pose no risks to terrestrial and aquatic organisms from the proposed use pattern. The use should provide non-target organisms extremely limited access to the chemical.

ENVIRONMENTAL FATE

No data is needed at present for this indoor-non food use site. Submitted hydrolysis data indicates that MNDA is a nominal concentration of 30 mg/L, hydrolytically stable in pH 5, 7, and 9 sterile, aqueous buffer solutions incubated in darkness at 25° C ±1 for 30 days.

Ecological Effects Likelihood of Adverse Effects on Non-Target Organisms

Terrestrial Organism Toxicity Avian Subacute Dietary Toxicity The LC_{5O}`s fall above 5000 ppm, MNDA is practically non-toxic to avian species on a subacute dietary basis. Since the avian dietary studies indicate MNDA is not toxic, no further avian testing is needed for the proposed indoor use.

Aquatic Organism Toxicity

Freshwater Fish Acute Toxicity

The LC_{5O}'s fall in the range of 72.0-90.0 ppm, MNDA is slightly toxic to freshwater fish on an acute basis. The guideline (72-1) is not fulfilled until information on % AI of the test material is submitted. A supplemental 14-day semi-static toxicity study indicate that the LOEC was 39 ppm and the NOEC was

20 ppm. Therefore, prolonged exposure does not significantly increase the hazard of this chemical to fish.

Freshwater Invertebrates

The LC_{5O}/EC_{5O} is 130 mg/L, MNDA is practically non-toxic to aquatic invertebrates on an acute basis. The guideline (72-2) is not fulfilled until the % AI used under test conditions is submitted.

Invertebrate life-cycle

A study indicates that the MATC of 54.8 mg/L, a LOEC of 77.9 mg/L and a NOEC of 38.5 mg/L with the most sensitive endpoints affected being reproduction and growth. An invertebrate life-cycle study is not required for the proposed indoor use of MNDA.

Toxicity to Plants

Phytotoxicity data is not required for the proposed indoor use of MNDA although two plant studies were submitted.

A study using freshwater green algae resulted in a 120 hr EC_{50} of 8.1 mg/L and an NOEC of 0.11 ppm.

Ecological Effects Risk Assessment

The Agency has reviewed the proposed Section 3 registration for the use of MNDA. Based on the ecological effects data submitted by the registrant, the Agency concludes that the product should pose no risks to terrestrial and aquatic organisms from the proposed use pattern. The proposed use should provide non-target organisms extremely limited access to the chemical.

Data Gaps

Toxicology

The toxicology data base on MNDA is adequate as defined for a non-food use chemical in 40 CFR Part 158. There is additional confirmatory data required from the registrant for two developmental studies, and these data are not expected to alter the conclusions of the studies.

Environmental Fate

The percent active ingredient of the test material is required as supplemental information to upgrade 3 studies to a guideline acceptable status.

Regulatory Conclusion

Technical/MUP Product - The Agency has determined that the database has been adequately addressed by the registrant to grant a conditional Section 3(c)(5)(b) registration on the technical/MUP product. Additional confirmatory data is required to upgrade all studies to guideline acceptable status.

For More Information

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For more information about EPA's pesticide registration program, MNDA, or of individual products containing MNDA, please contact the Registration Division (7505C), OPP, US EPA, Washington, DC 20460, telephone 703-305-5446.

For information about the health effects of pesticides, or for assistance in recognizing and managing pesticide poisoning symptoms, please contact the National Pesticides Telecommunications Network (NPTN). Call toll-free 1-800-858-7378, from 6:30 a.m. to 4:30 p.m. Pacific Time, or 9:30 a.m. to 7:30 p.m. Eastern Standard Time, seven days a week.